Application Serial No.: 10/628,223 Response dated August 4, 2005 Reply to Office Action of April 5, 2005 Docket No. P-5394/1C1

## **REMARKS**

Claims 1 and 8 have been amended to further clarify the invention (as suggested by the Examiner in the Office Action dated April 5, 2005) to specify that the outer shield is locked in the extended position to prevent reexposure of the puncture tip of the needle cannula. Support for this amendment can be found in Applicants' specification in paragraph [0044].

Claims 1-15 are pending in the application.

## Double Patenting Rejection

The Examiner rejected claims 1-15 under the doctrine of obviousness-type double patenting, as being unpatentable over claims 1-15 of U.S. Patent No. 6,623,461.

Applicants are filing a Terminal Disclaimer herewith, which addresses this rejection.

## Claims Rejection - 35 USC § 102

Claims 1, 3, 6, 8, 9, 11 and 13 are rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent # 4,326,519 to D'Alo et al., (D'Alo).

Applicants respectfully traverse this rejection in view of this amendment.

Of the claims rejected amended claims 1 and 8 are independent, with the remaining claims dependent thereon.

Amended claim 1 is directed to a needle assembly, comprising among other things:

wherein said first tab and said second tab are configured such that opposing forces applied against said first tab and said second tab cause said outer shield to move toward said distal end of said needle cannula from said retracted position to said extended position, such that said outer shield is locked in said extended position to prevent reexposure of said puncture tip of said needle cannula.

Amended claim 8 is directed to a shieldable blood collection set and similarly recites:

wherein said first tab and said second tab are configured such that opposing forces applied against said first tab and said second tab cause said outer shield to move toward said distal end of said needle cannula from said retracted position to said extended

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position, such that said outer shield is locked in said extended position to prevent reexposure of said puncture tip of said needle cannula.

In contrast to amended claims 1 and 8, the Examiner states in the Office Action of April 5, 2005 that "Reference numeral 12 is an indwelling catheter, not a shield. The catheter is supposed to slide right off the needle, exposing the needle." Thus as the Examiner observes, "D'Alo is not a shielding device."

Applicants respectfully point out that D'Alo fails to disclose at least the claimed feature of the needle shield remaining over the needle in the extended position to prevent reexposure of the puncture tip of the needle cannula. Thus, D'Alo does not anticipate amended claims 1 and 8.

For these reasons, applicant submits that amended claim 1 and 8 and dependent claims 3, 6, 9, 11 and 13 are not anticipated by the D'Alo reference.

Furthermore the invention defined by amended claims 1 and 8 is nether taught nor rendered obvious by D'Alo. D'Alo has no suggestion of a shielding device in which the needle shield locks in the extended position to prevent reexposure of the puncture tip of the needle cannula. In fact, D'Alo teaches away from applicants' invention as is related to an improved catheter in which the needle is adapted for insertion and removal from the catheter. Accordingly, it is submitted that the forward shielding safety device as defined by amended claims 1 and 8 is not taught or suggested by D'Alo.

## Claims Rejection - 35 USC § 103

Claims 7 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over D'Alo.

Applicants respectfully traverse this rejection in view of this amendment.

Of the claims rejected claim 7 is dependent on amended claim 1 and therefore includes all of the limitations of amended claim 1, claim 14 is dependent on amended claim 8 and therefore includes all of the limitations of amended claim 8. As discussed above D'Alo fails to disclose, teach or suggest the invention of claims 1 and 8 as amended.

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For this reason applicants submit that claims 7 and 14 are not rendered obvious by the D'Alo Reference.

In view of the amendment and remarks herein, applicant submits the claims are patentably distinct over the prior art and allowable in form.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 02-1666.

If the Examiner has any questions or comments relating to the present application, he or she is respectfully invited to contact Applicants' agent at the telephone number set forth below.

Respectfully submitted,

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